SUGAMNEAL™

Abridged Prescribing Information:

Sugamneal TM COMPOSITION: Each mL contains sugammadex sodium, 108.8 mg (equivalent to sugammadex, 100 mg).Pharmacotherapeutic group: Antidotes; ATC code: V03AB35. DESCRIPTION: 2 mL clear tubular sulphur treated vial with aluminum flip off seal in a carton. INDICATIONS: SUGAMNEAL is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. DOSAGE AND ADMINISTRATION: Administer SUGAMNEAL intravenously as a single bolus injection. The bolus injection may be given over 10 seconds into an existing intravenous line. From the time of SUGAMNEAL administration until complete recovery of neuromuscular function, monitor the patient to assure adequate ventilation and maintenance of a patent airway. Satisfactory recovery should be determined through assessment of skeletal muscle tone and respiratory measurements in addition to the response to peripheral nerve stimulation. The recommended dose of SUGAMNEAL does not depend on the anesthetic regimen. Recommended Dosing: SUGAMNEAL can be used to reverse different levels of rocuronium-or vecuronium-induced neuromuscular blockade. For rocuronium and vecuronium: (1) A dose of 4 mg/kg SUGAMNEAL is recommended if spontaneous recovery of the twitch response has reached 1 to 2 post-tetanic counts (PTC) and there are no twitch responses to train-of-four (TOF) stimulation following rocuronium-or vecuronium-induced neuromuscular blockade. (2) A dose of 2 mg/kg SUGAMNEAL is recommended if spontaneous recovery has reached the reappearance of the second twitch (T2) in response to TOF stimulation following rocuronium-or vecuronium-induced neuromuscular blockade. For rocuronium only: A dose of 16 mg/kg SUGAMNEAL is recommended if there is a clinical need to reverse neuromuscular blockade soon (approximately 3 minutes) after administration of a single dose of 1.2 mg/kg of rocuronium. Drug Compatibility: May inject SUGAMNEAL into the intravenous line of a running infusion with the intravenous solutions (0.9% sodium chloride, 5% dextrose, 0.45% sodium chloride and 2.5% dextrose, 5% dextrose in 0.9% sodium chloride, Isolyte P with 5% dextrose, Ringer's lactate solution, Ringer's solution) SUGAMNEAL is physically incompatible with verapamil, ondansetron, and ranitidine. CONTRAINDICATION: SUGAMNEAL is contraindicated in patients with known hypersensitivity to sugammadex or any of its components. WARNINGS AND PRECAUTIONS: Anaphylaxis and hypersensitivity, marked bradycardia, respiratory function monitoring during recovery, risk of, prolonged neuromuscular blockade, risk of recurrence of neuromuscular blockade due to displacement interactions, risk of recurrence of neuromuscular blockade with lower than recommended dosing, risk of recurrence of neuromuscular blockade due to the administration of drugs that potentiate neuromuscular blockade, risk of coagulopathy and bleeding, renal impairment, light anesthesia, reversal after rocuronium or vecuronium administration in the ICU, reversal of neuromuscular blocking agents other than rocuronium or vecuronium. ADVERSE REACTIONS: The serious adverse reactions are anaphylaxis and hypersensitivity, marked bradycardia. STORAGE: Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Protect from the light. When not protected from light, the vial should be used within 5 days. Keep out of reach of children. PATIENT COUNSELLING INFORMATION: Advise females of reproductive potential using hormonal contraceptives that SUGAMNEAL may reduce the contraceptive effect. Instruct females to use an additional, non-hormonal method of contraception for the next 7 days following SUGAMNEAL administration.Ref: 1. Cochrane Database of Systematic Reviews 2017, Issue 8. Art. No.: CD012763. DOI: 10.1002/14651858.CD012763 *As per prescribing information

Amneal Healthcare Private Limited
Regd. Office: 9th Floor, 901 To 905 Iscon Elegance, Circle P, S.G. Highway, Ahmedabad 380015
Corporate office: 15-16, Art Guild House, Phoenix Market City, Kurla, Mumbai - 400070
www.amneal.com